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EXAMINER
BLACKWELL RUDASIL, GWENDOLYN A

ART UNIT	PAPER NUMBER
1775	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,642

Applicant(s)

CASTRO ET AL.

Examiner

Gwendolyn A. Blackwell-Rudasill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 44-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6. 6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Upon further consideration Group II originally set forth as claims 44-58 and Group III originally set forth as claims 59-61 have been combined into Group II now claims 44-61.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-43, drawn to an aluminum oxide ceramic material, classified in class 428, subclass 542.8.
 - II. Claims 44-61, drawn to a method of making an aluminum oxide ceramic material, classified in class 419, subclass 49.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions of Group I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process. Instead of using subjecting the sintered ceramic material to hot isostatic pressing to densify the ceramic material, the ceramic material can be formed by using a modified Czochralski process as described in United States Patent no. 4,323,545 or using a slurry casting to make a shaped article instead of shaping a blank.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Steven Skolnick on August 27, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 44-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by a Master of Science thesis entitled *Fracture Characteristics, Hardness, and Grain Size of Five Polycrystalline Alumina Orthodontic Brackets*, Pham.

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Pham discloses that polycrystalline orthodontic brackets such as the Contour (manufactured by Class One Orthodontics) and the MXi (manufactured by TP Orthodontics) contain fine grains of alumina on the order of 0.57 ± 0.05 microns and 0.65 ± 0.08 microns, respectively, meeting the requirements of claims 1, 3-7 and 12-13, (page 29, Table 2). The surface roughness of the brackets are considered to correlate to the grain size of the alumina, meeting the requirements of claim 2, (page 26, lines 12-13).

Pham also discloses that the fracture toughness of the Contour and MXi brackets are $4.57 \pm 0.85 \text{ MPa}\cdot\text{m}^{1/2}$ and $3.58 \pm 0.23 \text{ MPa}\cdot\text{m}^{1/2}$, meeting the requirements of claims 8-9, (page 28, Table 1).

Although Pham does not specifically disclose the contrast ratio and the wet transmittance, absent an objective evidentiary showing to the contrary, keeping in mind that arguments are not evidence, a chemical composition and its properties are inseparable. *MPEP 2112.02*. Because the prior art exemplifies applicant's claimed composition in relation to the aluminum oxide material, the claimed physical properties relating to the contrast ratio and wet transmittance are inherently present in the prior art therefore not providing patentable distinction over the prior art.

9. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by European Patent Application Publication no. 0 284 418 B1, EP '418.

EP '418 discloses a translucent ceramic product made from aluminum oxide material with additives such as magnesia and yttria, (column 1, lines 11-16). The grains of the ceramic material are preferred to be less than 2 micrometers or less, (column 2, lines 24-25). Example 5, as shown in Figure 5, is made mostly of alumina with 0.05 magnesium oxide added having good

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translucence, an average grain size of less than 1.1 micrometers, and a flexure strength of 784.6 MPa, meeting the requirements of claims 1-9.

Although EP '418 does not specifically disclose the contrast ratio and the wet transmittance, absent an objective evidentiary showing to the contrary, keeping in mind that arguments are not evidence, a chemical composition and its properties are inseparable. *MPEP 2112.02*. Because the prior art exemplifies applicant's claimed composition in relation to the aluminum oxide material and flexure strength, the claimed physical properties relating to the contrast ratio and wet transmittance are inherently present in the prior art therefore not providing patentable distinction over the prior art.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-43 are rejected under 35 U.S.C. 103(a) as being obvious over United States Patent Application Publication no. 2003/0031984, Rusin et al in view of United States Patent no. 3,464,837, McLean et al.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

13. Rusin et al disclose crystalline ceramic mill blanks having a flexural strength of greater than about 250 MPa, (page 1, section 0006). The ceramic material has a contrast ratio of less

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than about 0.7 and is translucent, (page 2, section 0015). Dental devices such as restoratives, replacements, inlays, onlays, veneers, crowns, bridges, implants, and posts can be made formed from the ceramic material, (page 2, section 0023). The ceramic material can be polycrystalline, (page 2, section 0025), such as aluminum oxide, (page 3, section 002 having a purity of at least 99.5% with magnesium oxide being added to the aluminum oxide aiding in sintering and enhancing the strength of the aluminum oxide, if desired. A high purity aluminum oxide powder utilizing submicron size particles has been used to produce a substantially theoretical dense sintered compact, (page 3, section 0035). A dental mill blank can be mounted to a holder such as a stub, (page 4, section 0040). Preferably the surface of the blank is smooth and non-tacky, (page 3, section 0041). Coloring of the mill blank to more closely resemble the color of the underlying tooth structure can be accomplished by using certain types of luting or bonding composites or cements whereby a colored composition (cement, paste, gel, etc.) is adhered to the prosthesis to the underlying tooth structure or a color or shading composition can be added to the surface of the milled prosthesis, (page 4, sections 0047, 0049). In addition, the crystalline ceramic mill blank can be provided in kit-form with one or more blanks, along with instructions for using the blanks, a color matching composition, a bonding agent, and a milling lubricant, (pages 4-5, sections 0050-0051). The average grain size of the ceramic material of Rusin et al is greater than that exemplified by Applicant.

While Rusin et al do not specifically disclose the transmittance of the ceramic material, the transmittance would be present in the ceramic material because the contrast ratio for the ceramic material is the same as that exemplified by Applicant.

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McLean et al disclose dental materials used in the construction of artificial teeth and reinforcements, crowns, inlays, bridge pontics and dental enamel veneers, (column 1, lines 22-32). The dental materials are made of refractory oxide particles of a size 60 microns or less, (column 2, lines 22-27). Aluminum oxide can be used as the dental material, (column 2, lines 28-48). McLean does not specifically disclose the grain size of the aluminum oxide as exemplified by Applicant, the contrast ratio, transmittance, or the use of the dental material in a dental kit.

The inventions as disclosed by Rusin et al and McLean et al are drawn towards ceramic materials used in the making of dental prostheses. McLean disclose that the oxide particles should be 60 microns or less, (column 2, lines 22-23). It would have been obvious to one skilled in the art to modify the grain size, without undue experimentation, which is considered equivalent to particle size, of Rusin et al to a range as exemplified by Applicant, 60 microns or less, to create a polycrystalline ceramic material that increases the strength of the resulting specimen while decreasing the particle size and decreasing the light transmission, (column 2, lines 23-35).

14. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application Publication no. 0 284 418 B1, EP '418.

EP '418 discloses a translucent ceramic product made from aluminum oxide material with additives such as magnesia and yttria, (column 1, lines 11-16). The grains of the ceramic material are preferred to be less than 2 micrometers or less, (column 2, lines 24-25). Example 5, as shown in Figure 5, is made mostly of alumina with 0.05 magnesium oxide added having good translucence, an average grain size of less than 1.1 micrometers, and a flexure strength of 784.6

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MPa. EP '418 does not specifically show examples demonstrating that the grain size is less than 1 micrometer or the contrast ratio.

Based upon the teachings of EP '418 it would have been obvious to one skilled in the art to optimize the grain size of the ceramic material through routine experimentation to create grain sizes that are fine and uniform having a high hardness and superior light transmissibility, (column 2, lines 7-13).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

United States Patent no. 6,482,284, disclose a dental mill blank and a support stub assembly.

United States Patent no. 5,217,375, disclose artificial onlay tooth crowns and inlays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwendolyn A. Blackwell-Rudasill whose telephone number is (703) 305-9741. The examiner can normally be reached on Monday - Thursday; 6:00 am - 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on (703) 308-3822. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Gwendolyn A. Blackwell-Rudasill
Examiner
Art Unit 1775

GBR
gbr


DEBORAH JONES
SUPERVISORY PATENT EXAMINER